

The rejection of Claims 11, 15-18, 22-25, 29, 31-32, and 36-37 under 35 U.S.C. § 102(b) over Bengmark et al is believed to be obviated by the amendment above. Further, the rejection over Bengmark et al. is traversed below.

Bengmark et al only describes a method of growing *Lactobacillus plantarum* 299v in the stomachs of mammals. Therefore, Bengmark et al merely demonstrates that *Lactobacillus plantarum* 299v may be cultured in the stomachs of mammals.

In contrast, the claimed invention relates to methods of reducing a level of at least one oxidative stress factor in the blood of a mammal, increasing a level of the fecal concentration of propionic acid in a mammal, and reducing a level of adhesion of monocytes to endothelial cells in a mammal by administering *Lactobacillus plantarum* 299v to a mammal in need thereof. Further, the reducing and/or increasing capabilities of such levels are specified to be compared to those levels in which the *Lactobacillus plantarum* 299v is not present, providing a reasonable benchmark and/or baseline.

In light of the above, there are key differences between the disclosure of Bengmark et al and the claimed invention. First, Bengmark et al merely discloses, at best, that it is possible to grow *Lactobacillus plantarum* 299v in any mammal. According to this disclosure, any mammal may be used. Alternatively, the claimed invention provides administering *Lactobacillus plantarum* 299v to a mammal in need thereof such reducing and/or increasing capabilities of *Lactobacillus plantarum* 299v, requiring the identification of such a mammalian population. Accordingly, Bengmark et al fails to appreciate these capabilities; and therefore, fails to disclose selecting a mammalian population in need thereof such reducing and/or increasing capabilities of *Lactobacillus plantarum* 299v. The selection of such mammals in need thereof, followed by the claimed administration of *Lactobacillus plantarum* 299v to this population is clearly not intended, appreciated, and certainly not

inherent to a method of merely growing *Lactobacillus plantarum* 299v in all mammals (see Bengmark et al).

The CAFC has recently ruled in a case having similar claim language as the present application (See the attached copy of Rapoport v. Dement, 59 USPQ2d 1215 (CAFC 2001)). In Rapoport, the Court determined that a method for the treatment of sleep apneas fails to include the treatment of anxiety because the method of treatment of sleep apneas requires the identification of “a patient in need of such treatment” (see page 8, lines 9-13, and page 9, lines 25-27, of Rapoport). The Court explained that the basis of its decision relied on the fact that the “treatment of sleep apneas” was included “as a limitation” because the phrase “‘to a patient in need of such treatment’ would not have proper antecedent basis” otherwise (see page 8, lines 9-13, of Rapoport). Therefore, according to the Rapoport Court one must identify a “patient in need of such treatment” in order to treat the underlying phenomena.

Like Rapoport, the present invention relates to a method which contains the identification of “a mammal in need thereof”. Therefore, the identification of a population of mammals in need of such reducing and/or increasing capabilities of *Lactobacillus plantarum* 299v is also included in this presently claimed method. It is clear that Bengmark et al fails to select the claimed mammalian population; and therefore, does not disclose or suggest all of the claim limitations in the present invention. Therefore, Bengmark et al. alone can not sustain a *prima facie* of obviousness case since all of the claim limitations must be taught in order to do so, and it is certainly impossible for Bengmark et al. to anticipate the claimed invention.

The Office has indicated that the claimed invention is inherent. However, the Office has not put forth any evidence whatsoever to support its contention. The MPEP requires the Office to rely on “facts”, other than those provided in the specification of the pending application, to support a conclusion that a claimed invention is inherent. However, no facts

have been provided. The Office has merely provided a blanket statement lacking facts for the Applicants to consider and argue. Lacking such facts, how can the Applicants refute the inherency contention?

Further, the Office has relied on volumes of case law to support the inherency contention. However, it appears that the distinction between the case law and the present application is that the claimed invention is a method, not a composition. More specifically, at page 6, line 1, the Office contends that “a discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer”. One key difference is that the claimed invention is not a composition. The above-mentioned case law may apply to a claimed composition; however, a discoverer may claim a novel method of using a composition. Therefore, the Office clearly mis-characterized the claimed invention and applies inappropriate case law.

The Office contends that timing and dosage requirements are required in order to place the claimed invention in condition for allowance (see page 7, lines 10-17, of the Office Action.). However, the Office’s attention is directed to thousands of patents that have issued over the years containing claimed methods of use absent timing and dosage requirements. In fact, the Examiner has allowed many patents to issue, including the enclosed US Patent No. 6,294,166, which is absent timing and dosage requirements. Further the methods of use claims on US Patent No. 6,294,166 do not provide even provide a baseline for the claimed reducing and/or increasing capabilities of the claimed composition. Therefore, the above-mentioned requirements appear to be arbitrary, lacking any consistency with precedent set by the Office. Accordingly, it appears as if the Office’s argument can not be sustained.

In light of the above, Applicants respectfully submit that Bengmark et al. does not disclose or suggest the claimed invention. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 11 and 15-37 under 35 U.S.C. § 112, second paragraph, is obviated by the above amendment. The Office contends that the words “reducing” and/or “increasing” is vague, indefinite and confusing. Further, the Office contends “effective amount” is confusing. The Office further contends that “cancer” is not “an inflammatory disease”. Finally, the Office contends that timing and dosage requirements are required.

The above amendment removes the phrase “effective amount”.

Further, the Office’s attention is directed to thousands of patents that have issued over the years containing claimed methods of use absent timing and dosage requirements. In fact, the Examiner has allowed many patents to issue, including the enclosed US Patent No. 6,294,166, which is absent timing and dosage requirements. Further the methods of use claims US Patent No. 6,294,166 do not provide even provide a baseline for the claimed reducing and/or increasing capabilities of the claimed composition. Once again, the above-mentioned requirements appear to be arbitrary, lacking any consistency with precedent set by the Office. Accordingly, it appears as if the Office’s argument on these grounds can not be sustained.

Finally, the Office permits the Applicant to be a lexicographer unless the definition of a term is repugnant to the generally accepted definition. It appears as if the Office is challenging Applicants inclusion of “cancer” as “an inflammatory disease”. However, the Office has not put forth any “fact” whatsoever to demonstrate that “cancer” being included as “an inflammatory disease” would be repugnant to the state of the technical field. The Office must provide such “facts” in the form of a reference in order to sustain the rejection. The Office is reminded that if mere general knowledge is being relied upon, Applicants may

request the Office to present "facts" to demonstrate such knowledge. These facts have not been presented thus far.

In light of the above, Applicants respectfully request withdrawal of these grounds of rejection.

Applicants respectfully submit that the present application is now in condition for allowance. Favorable reconsideration is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact Applicants' attorney by telephone.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Norman F. Oblon  
Attorney of Record  
Registration No. 24,618

Thomas W. Barnes III, Ph.D.  
Registration No. ~~P~~52,595



**22850**

Tel.: (703) 413-3000  
Fax: (703) 413-2220  
NFO:DJP:TWB/la  
I:\atty\Twb\204742us-am-b.wpd

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Amendment Filed on:

HEREWITH

IN THE CLAIMS

Please amend the claims as follows.

--11. (Twice Amended) A method of reducing [the levels] a level of at least one oxidative stress factor in the blood of a mammal, comprising administering to a mammal in need thereof [an effective amount] of *Lactobacillus plantarum* 299v, wherein the level of the at least one oxidative stress factor is reduced compared to the level of the at least one oxidative stress factor in the absence of *Lactobacillus plantarum* 299v.

24. (Amended) A method of increasing [the levels] a level of the fecal concentration of propionic acid in a mammal, comprising administering to a mammal in need thereof [an effective amount] of *Lactobacillus plantarum* 299v, wherein the level of the fecal concentration of propionic acid is increased compared to the level of the fecal concentration of propionic acid in the absence of *Lactobacillus plantarum* 299v.

31. (Amended) A method of reducing [the] a level of adhesion of monocytes to endothelial cells in a mammal, comprising administering to a mammal in need thereof [an effective amount] of *Lactobacillus plantarum* 299v, wherein the level of adhesion of monocytes to endothelial cells is reduced compared to the level of adhesion of monocytes to endothelial cells in the absence of *Lactobacillus plantarum* 299v.--

Claims 38-40 (New).